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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/932,302	08/17/2001	Bertha K. Madras	56,007-CIP (70207)	5385

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EXAMINER
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HARTLEY, MICHAEL G

ART UNIT	PAPER NUMBER
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1616

DATE MAILED: 07/24/2003

14

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/932,302

Applicant(s)

MADRAS ET AL.

Examiner

Michael G. Hartley

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 30 May 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-35 is/are pending in the application.
- 4a) Of the above claim(s) 6-9, 11-13, 18-26 and 30-35 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-5, 10, 14-17 and 27-29 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 6-8.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

***Election/Restrictions***

Applicant's election of Group I in Paper No. 10 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Applicant's election of species of <sup>123</sup>I-altropane is further acknowledged. The traversal is not found persuasive because the examiner can request an election of species anytime the claims encompass more than a reasonable number of species. The applicant's claims include the use of a large number of species, as shown by the formula on page 8, as well as in claims 6-9 and 11-13. It is noted that a C-11 labeled agent is classified in 424/1.81, while iodine labeled agents are in 424/1.85, etc. Claims 6-9 and 11-13 are withdrawn are not being drawn to the elected species.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-5, 10, 14-17 and 27-29 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 2 and 27 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: 1) administration of a labeled dopamine transporter and 2) assessment by PET or SPECT imaging. For example, claim 1 recites only an analytical (or mental) step of "assessing" and such a step would require the collection of some data to which the "assessing" is performed. However, claim 1 has no step of collecting the data which is being assessed. Thus, claim 1 is missing essential steps because only an analytical step is recited. Thus, it is unclear what is being claimed, i.e., an in vivo method, an in vitro assay, etc. In claim 2, PET or SPECT are used; however, such radioimaging methods require the administration of a radiolabeled compound and this step is missing in claims 1 and 2.

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The dependent claims fall therewith. Combining the method steps of claims 1-3 into claims 1 and 27, accordingly, may obviate these rejections.

Claim 4 recites the limitation "the amount of labeled dopamine transporter ligand" in line 2. There is insufficient antecedent basis for this limitation in the claim. It appears that this claim should be dependent on claim 3 and not claim 2, as claims 1-2 do not state "labeled dopamine transporter ligand."

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-5, 14-17 and 27-29 are rejected under 35 U.S.C. 102(e) as being anticipated by Kuhar (US 6,531,483).

Kuhar discloses methods of diagnostic imaging comprising administering a dopamine transporter ligand (i.e., a radiolabeled tropane compound) and performing imaging thereof, see columns 1-2. The tropane compounds may be labeled with various nuclides for detection by PET or SPECT, including, <sup>123</sup>I, see column 2. Kuhar teaches that the for detection of attention deficient disorders, see abstract and column 2, lines 24-29. Diagnostic methods are disclosed in columns 7+, which would include the use of controls, etc. to determine the binding to the dopamine transporter.

Claims 1, 14 and 27 are rejected under 35 U.S.C. 102(b) as being anticipated by Blum (US 5,500,343).

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Blum discloses methods for detecting the susceptibility to a disorder comprising assessing the dopamine transporter, see abstract. The disorders include ADHD, see column 6,, lines 4-6. The dopamine transporter is assessed through DNA; however, dopamine is associated with the CNS, see column 1. The methods may be used for diagnosis of the disorders, see column 1.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-5, 10, 14-17 and 27-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kuhar (US 6,531,483) in view of Elmaleh (US 5,493,026).

Kuhar discloses methods of diagnostic imaging of attention deficit disorders comprising administering a radiolabeled tropane compound and performing imaging thereof, as set forth above.

Kuhar fails to specifically disclose the use of applicant's elected dopamine receptor ligand, <sup>123</sup>I-altropane. However, <sup>123</sup>I-altropane is a known dopamine transporter ligand which is safe and effective for diagnostic imaging, as shown by Elmaleh.

Elmaleh teaches <sup>123</sup>I-altropane is an especially effective dopamine transporter ligand which can be used for diagnostic methods using PET or SPECT, see columns 2 and figure 3.

It would have been obvious to one of ordinary skill in the art to substitute <sup>123</sup>I-altropane for the dopamine transporter ligand in the method of screening for attention deficit disorders disclosed by Kuhar because Kuhar teaches that various tropane compounds may be employed, and Elmaleh teaches that <sup>123</sup>I-altropane is an especially useful dopamine transporter ligand for diagnostic methods involving dopamine transporter using radioimaging methods.

***Conclusion***

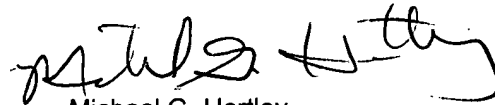
No claims are allowed at this time.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael G. Hartley whose telephone number is (703) 308-4411. The examiner can normally be reached on M-F, 7:30-5, off alternative Mondays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (703) 308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and (703) 308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.



Michael G. Hartley  
Primary Examiner  
Art Unit 1616

MH  
July 21, 2003